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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lasse L. Hessel

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EXAMINER

HEWITT, JAMES M

ART UNIT

PAPER NUMBER

3679

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/773,697	Applicant(s) HESSEL ET AL.	
	Examiner James M. Hewitt	Art Unit 3679	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 15-18 and 26-38 is/are rejected.
- 7) ☒ Claim(s) 8,11-14 and 19-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species II in the reply filed on 11/3/05 is acknowledged. The traversal is on the ground(s) that the restriction should be modified to include examination of Figures 17-26, or the claims corresponding to these figures. This is found persuasive, and claims 1-4, 7-8 and 11-38 will be treated on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-6 and 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/3/05.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed on 8/8/01. It is noted, however, that applicant has not filed a certified copy of the PCT/DK01/00529 application as required by 35 U.S.C. 119(b). **Drawings**

The drawings are objected to because: in Figure 7, lowermost numeral '34' should be '37'; reference numeral '38' is not shown in the drawings, particularly Figures 8-16; in Figure 12, it is unclear as to why there are two sets of reference numerals '40' and '41'. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in

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reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper format for an abstract of the disclosure.

The abstract should be generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Claim Objections

Claims 1-4, 7-8 and 11-38 are objected to because of the following informalities:

In claim 1, line 3, "a" should be deleted.

In claim 1, line 4, "respectively" should be deleted.

In claim 1, line 10, the phrase "coupling collar of this disc" should be replaced with "first coupling collar".

In claim 1, line 12, the phrase "via the coupling" should be inserted after "coupled".

In claim 3, lines 1-2, "the free end face of the radial exterior wall of the coupling groove" lacks proper antecedent basis. It is suggested that the phrase "of the radial exterior wall" be deleted.

In claim 3, line 2, "abuts closely" is unclear. It is unclear as to how "closely" can modify or describe "abuts". If one object abuts another, it is in contact with and thus close to the other object. It is suggested that "closely" be deleted.

In claim 3, line 3, the phrase "via the coupling" should be inserted after "coupled".

In claim 4, line 2, the phrase "its radial interior wall" should be replaced with "the radial interior wall of the coupling groove".

In claim 7, line 3, "respectively" should be deleted.

In claim 8, line 1, "the radial inside face" should be "a radial inside face".

In claim 12, line 2, the phrase "facing in opposite directions and placed on each their" should be replaced with the phrase "each extending from a respective".

In claim 12, line 3, the phrase "pointing inwards and issuing from" should be replaced with the phrase "extending inward of".

In claim 12, line 3, "serving for" should be replaced with "for respectively".

In claim 12, line 4, "outwards" should be "outward".

In claim 14, line 4, the phrase "via the coupling" should be inserted after "coupled".

In claim 19, line 2, "via the coupling" should be inserted after "coupled".

In claim 19, lines 2-3, it is unclear as to how the coupling can be said to be arranged opposite the hinge of the second coupling part when the coupling comprises the second coupling part.

In claim 19, line 3, "the hinge" lacks proper antecedent basis.

In claim 20, line 3, "via the coupling" should be inserted after "coupled".

In claim 21, line 3, "via the coupling" should be inserted after "coupled".

In claim 22, line 3, "when mounted" should be deleted.

In claim 24, line 2, it is unclear as to what "its axis" modifies or refers.

In claim 24, line 3, "outwards in continuation of" should be "outwards of and continuous with".

Claim 27 should depend from claim 26 in order for "the implant" to have proper antecedent basis.

In claim 28, line 2, "the outer side" should be "an outer side".

In claim 28, line 2, "the radial first section" lacks proper antecedent basis.

Claim 29 and its dependents should be written to recite active steps. For instance: A method for application of a coupling according to claim 1, comprising the steps of: joining the two discs of the second coupling part; placing the second coupling inside a pouch, etc.

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In claim 29, lines 2-3, the recited pouch should be related to one of the first and second devices recited in claim 1.

Claims 30-34 should also recite active steps, and the claims should recite "further comprising the step of" is reciting an additional step, or if relating or expounding on a step already recited in claim 29, should state for example, "wherein the step of joining the two discs of the second coupling part comprises..."

In claim 31, lines 2-3, "the guide groove" lacks antecedent basis.

In claim 31, line 3, is open relative to what? What is meant by stating the second is open?

In claim 31, line 4, is closed relative to what? What is meant by stating the second is open?

In claim 32, lines 1-2, "the parts" should be "the coupling parts".

In claim 32, line 2, "the engagement" lacks proper antecedent basis.

In claim 33, line 1, "the engagement" lacks proper antecedent basis.

In claim 34, line 1, "the engagement" lacks proper antecedent basis.

As to claim 35, the claimed ostomy pouch should be related to the pouch recited in claim 29 and one of the first and second devices recited in claim 1. Claim 29 is drawn to a method of applying a coupling. How can such a method be used to obtain an ostomy pouch?

Claim 36 and its dependents should be written to recite active steps.

In claim 36, lines 1-2, it is unclear as to what "and an ostomy pouch" modifies. The Examiner suggests deleting the phrase "and an ostomy pouch" to make clear that the claim is drawn to a method and not to a product.

In claim 37, line 1, "the engagement" lacks proper antecedent basis.

In claim 38, line 1, "the engagement" lacks proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 15, 17 and 26-38 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,785,695 (Sato et al).

With respect to claim 1 and with particular reference to Figure 5, Sato et al disclose a coupling for detachably coupling first and second devices comprising: a first coupling part (on left side of Figure 5) on the first device and a second coupling part on the second device, with the first coupling part having a circumferential coupling groove (17) defined by a radial interior and exterior walls respectively and ending in a free end face facing in the opposite direction of the first device, and the second coupling part including first and second discs (7, 19) each having an aperture, and first and second coupling collars (inner collar of first disc and outer collar of second disc) respectively designed around the apertures of the first and second discs and extending mainly in a

cross direction of each respective disc, wherein the second coupling collar extends through the aperture of the first disc in the same direction as the coupling collar of this disc, and the two coupling collars of the second coupling part extend into and engage the circumferential coupling groove of the first coupling part when the devices are coupled.

With respect to claim 2, wherein the radial exterior wall of the coupling groove includes a circumferential projection (bulb) facing radially inwards and defining an offset.

With respect to claim 3, wherein the free end face of the radial exterior wall of the coupling groove abuts closely against the first disc when the devices are coupled.

With respect to claim 4, wherein the radial exterior wall of the coupling groove is longer than its radial interior wall when viewed in cross section.

With respect to claim 7, wherein the first and second coupling collars are arranged to be pressed together between the radial interior wall and exterior wall of the first coupling part when the devices are coupled.

With respect to claim 15, wherein the first disc has a greater diameter than the second disc.

With respect to claim 17, wherein at least the second disc is reinforced with at least one circumferential rib (inner collar of second disc)

With respect to claim 26, wherein the first coupling part is an implant for implantation around a stoma of an animal or human body.

With respect to claim 27, wherein the second coupling part is placed inside a pouch (10) for coupling with the implant with the coupling collars extending out through an aperture in the pouch.

With respect to claim 28, wherein an inside of an edge section along the aperture of the pouch is closely joined with the outer side of the radial first section of the first disc.

With respect to claim 29, Sato et al disclose a method for application of a coupling according to claim 1, wherein the two discs of the second coupling part are joined, the second coupling part is placed inside a pouch, and the inside of an area around an aperture of the pouch is joined with and fastened to the first disc with the coupling collars extending out through the aperture of the pouch.

With respect to claim 30, wherein the two coupling collars of the second coupling part together are pushed into the coupling groove of the first coupling part.

With respect to claim 31, wherein the radial exterior wall of the first coupling part forming the radial outer definition of the coupling groove is placed in a guide groove in the first disc of the second coupling part while the second coupling part is open, and the second coupling part then is closed.

With respect to claim 32, which further comprises uncoupling the parts by releasing the engagement between the two coupling parts by manipulation of the first disc.

With respect to claim 33, wherein the engagement between the two coupling parts is released by distally displacing the first disc.

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With respect to claim 34, wherein the engagement between the two coupling parts is released by affecting the first disc with radially opposite compressive forces in peripheral areas.

With respect to claim 35, Sato et al discloses an ostomy pouch (10) obtained by the method according to claim 29.

With respect to claim 36, Sato et al discloses a method for application of the coupling according to claim 1 and an ostomy pouch, wherein the first coupling part in the form of an annular implant having a projecting section with the coupling groove is implanted around a stoma, and an ostomy pouch (10) is coupled to the implant by the two coupling collars of the second coupling part being pushed into the coupling groove of the first coupling part.

With respect to claim 37, wherein the engagement between the two coupling parts is released by manipulation of the first disc.

With respect to claim 38, wherein the engagement between the two coupling parts is released by manipulation of locking means (collars and groove) for disengaging a lock between the first and the second disc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,785,695 (Sato et al).

Regarding claim 16, Sato et al fail to teach that the second disc is more rigid than the first disc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second disc of a material more rigid than the first since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 18, Sato et al fail to teach that the first disc is made of a transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first disc of a transparent material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Allowable Subject Matter

Claims 8, 11-14 and 19-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note that the allowability of the above claims is also contingent upon overcoming the above-noted objections (see ***Claim Objections*** above).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Hewitt whose telephone number is 571-272-7084.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Stodola can be reached on 571-272-7087. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JAMES M. HEWITT
PRIMARY EXAMINER